

69553-1

8/2/2013

1/12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 2 2013

Andermatt Biocontrol AG
c/o Mr. Frederick T. Smith, Agent
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Re: Madex HP
EPA Reg. No. 69553-1
Submission dated 2/25/2013 and subsequent revisions
Decision No. 475931

Dear registrant:

The Agency has reviewed your request to amend the subject product registration which includes the following changes to the product label:

Addition of OMRI and organic claims.

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5) is acceptable provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Before sale and distribution, ensure that the correct establishment number appears on the label or the immediate container in accordance with 40 CFR 156.10(f). To verify that the establishment number for a given facility is correct, check with the appropriate compliance contact based on the location of the establishment. Contacts are listed at <http://www.epa.gov/compliance/contact/monitoring-establish.html>.
3. Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

ONCURRENCES

SYMBOL	▶	7511P	7511P						
SURNAME	▶	Subold	Boley						
DATE	▶	8/2/13	8/2/13						

If you have questions, please contact Ann Sibold by phone at 703 305-6502 or by email at sibold.ann@epa.gov.

FEB 8 2012

Sincerely,



Kimberly Nesci
Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (Mail Code 7511P)

Enclosures (2):
A-79
Stamped Label

4/12

Master Label

SUBLABEL A: Agricultural Use

MADEX HP

Biological Insecticide for Control of the Codling Moth and Oriental Fruit Moth



FOR ORGANIC PRODUCTION



Active Ingredient*:

Cydia pomonella granulovirus isolate V22

0.06%

Other Ingredients:

99.94%

Total:

100.00%

*Contains a minimum of 3×10^{13} viral occlusion bodies per liter.

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/INSIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents:

Lot No.:

EPA Reg. No. 69553-1

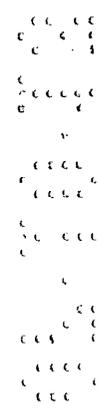
EPA Est. No.

Manufactured by: Andermatt Biocontrol AG

Stahlermatten 6

CH-6146 Grossdietwil

Switzerland



PRECAUTIONARY STATEMENTS
Hazards To Humans and Domestic Animals

CAUTION. Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes or clothing, and breathing spray mist. Causes moderate eye and skin irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
If on skin:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- waterproof gloves
- shoes plus socks

Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Repeated exposures to high concentrations of microbial proteins can cause allergic sensitization.

Engineering Controls

When handlers use closed systems or enclosed cabs in a manner that meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours unless wearing appropriate PPE.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION

MADEX HP acts very specifically against larvae of the apple codling moth, *Cydia pomonella*, and the Oriental fruit moth, *Grapholita molesta*, as a pre-harvest biological insecticide on pome and stone fruit trees including apple, quince, pear, peach, nectarine, apricot, plum, cherry, walnut, almond, pluot, and aprium. After ingestion by the larva, the virus multiplies within the cells of the host insect causing a fatal infection. Rapid virus multiplication within the host cells results in cell destruction and death of the organism, typically within 3-7 days.

Start spraying shortly before larvae hatch from the eggs and before the larvae feed their way into the fruit. In general, one to two sprays per generation are generally sufficient. Due to unfavorable weather conditions, flight, egg laying, and hatching may extend over a longer period of time and up to 6 applications may be needed. Frequent applications at low rates may be more effective than one or two applications at high rates.

Use Restriction

Do not apply this product through any type of irrigation system.

MIXING AND APPLICATION INSTRUCTIONS

Mix MADEX HP with water and apply as a spray to fruit and foliage of trees in orchards and nurseries. Use water at or near neutral pH (7).

CROP	RATE	COMMENTS
Pome and Stone fruit trees including apple, quince, pear, peach, nectarine, apricot, plum, prunes cherry, walnut, almond, pluot, and aprium	0.5 - 3.0 fluid ounces per acre, depending on pest pressure and application frequency.	<p>Select a spray volume appropriate to tree size and density of foliage. For small trees use 50-100 gallons of water per acre. Larger trees with denser canopies require 100-200 gallons per acre.</p> <p>Consult your local Cooperative Extension Service if you need advice about how to attain good spray coverage in your orchard.</p> <p>Make at least two (2) applications of MADEX HP per codling moth or Oriental fruit moth larval generation. Target small larvae early in their life cycle. Repeat as necessary to maintain control. MADEX HP breaks down under direct exposure to sunlight. If moths are still flying and laying eggs, reapply after 6-8 sunny days (counting 2 partially sunny days as 1 sunny day).</p>

MADEX HP can be applied up to and including the day of harvest.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE:

Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 41°F (5°C). Bioactivity may be impaired by storage above 86°F (30°C). Storing the product under cold or freezing temperatures will extend its shelf life.

PESTICIDE DISPOSAL:

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by State and local ordinances.

WARRANTY

Andermatt Biocontrol AG warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. To the extent consistent with applicable law, **NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.**

Sublabel B: Residential Use

MADEX HP

Biological Insecticide for Control of the Codling Moth and Oriental Fruit Moth

 **FOR ORGANIC GARDENING**



Active Ingredient*:

Cydia pomonella granulovirus isolate V22

0.06%

Other Ingredients:

99.94%

Total:

100.00%

*Contains a minimum of 3×10^{13} viral occlusion bodies per liter.

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Net Contents:

Lot No.:

EPA Reg. No. 69553-1

EPA Est. No.

Manufactured by: Andermatt Biocontrol AG

Stahlermatten 6

CH-6146 Grossdietwil

Switzerland

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FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
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If inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.

ENVIRONMENTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

MADEX HP acts very specifically against larvae of the apple codling moth, *Cydia pomonella*, and the Oriental fruit moth, *Grapholita molesta*, as a pre-harvest biological insecticide on pome and stone fruit trees including apple, quince, pear, peach, nectarine, apricot, plum, cherry, walnut, almond, pluot, and aprium. After ingestion by the larva, the virus multiplies within the cells of the host insect causing a fatal infection. Rapid virus multiplication within the host cells results in cell destruction and death of the organism, typically within 3-7 days.

Start spraying shortly before larvae hatch from the eggs and before the larvae feed their way into the fruit. In general, one to two sprays per generation are generally sufficient. Due to unfavorable weather conditions, flight, egg laying, and hatching

may extend over a longer period of time and up to 6 applications may be needed.

Use Restrictions

For use only on pome and stone fruit trees in residential settings. Not for use on trees or fruit grown for sale or other commercial use.

MIXING AND APPLICATION INSTRUCTIONS

MADEX HP must be mixed with water and applied as a spray to the fruit and foliage of pome and stone fruit trees (apple, quince, pear, peach, nectarine, apricot, plum, cherry, walnut, and almond).

Mix 1/2 teaspoon of MADEX HP per 5 gallons of water and apply directly to each tree using a hand pump sprayer or other suitable spray equipment. Spray a sufficient volume to thoroughly wet all leaves and fruit with minimal run-off or dripping.

Apply MADEX HP first in late spring or early summer, when eggs of the first generation of codling moth or Oriental fruit moth begin to hatch. Apply MADEX HP at least twice during each larval generation. When pest pressure persists, make additional applications of MADEX HP in mid- to late summer. Consult your local Cooperative Extension Service for more information about the best timing of codling moth and Oriental fruit moth sprays.

MADEX HP breaks down under direct exposure to-sunlight. If moths are still flying and laying eggs, reapply after 6-8 sunny days (counting 2 partially sunny days as 1 sunny day).

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE:

Keep in original container. Store away from direct sunlight, feed, or foodstuffs. Keep container tightly sealed when not in use. Store at temperatures below 41°F (5°C). Bioactivity may be impaired by storage above 86°F (30°C). Storing the product under cold or freezing temperatures will extend its shelf life.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. Do not reuse or refill container.

If empty:

Place in trash or offer for recycling, if available.

If partly filled:

Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

Andermatt Biocontrol AG warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. To the extent consistent with applicable law, NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.